WSA 2003 Proposed Publication Project

Publication Name:	Characterization of enzyme induction as an early biomarker of potential harm (N01460)
Brief Description of Project:	Enzymatic induction may be related to disease risk and might indicate acquired changes in susceptibility (IOM Chapter 11). A thorough literature search will be conducted to identify various methods used for phenotyping and/or genotyping of enzymes induced by cigarette smoke and their potential use as early biomarkers of potential harm. The methods will measure enzyme induction either through changes in functional activity using probe substrates (phenotype) or through changes in expression using microarray assays and proteomics. The methods will be developed and validated at academic sites or at a CRO. Characterization of the feasibility of these methods as biomarkers of potential harm will be conduced on banked samples from the ACCORD JLI Long Term Study. The validity of both phenotype and proteomic based assays in PREP assessments will be compared and assessed.
Type of Deliverable(s):	Publication
Program Area: (Check all areas that apply)	☒ Cancer ☐ CVD ☐ COPD ☐ Repro ☐ ETS ☐ Determinants of Smoke Exposure ☐ Product Design Guidance ☐ PI Specific Projects ☒ CE Specific Projects ☐ Sensory Specific Projects ☐ Scientific Affairs & Communication Specific Projects ☐ WSA PMI Specific Projects (Neuchatel & Asia) ☐ PMRL Specific Projects (Germany & Belgium)
Project Leader:	Mohamadi Sarkar
Internal/External Authors and Affiliation:	
Prioritization:	☐ Critical ☒ Priority ☐ Secondary ☐ Low

Milestones:	Target Date:
1. Introduction/Background	May 31, 2003
2. Methods	July 31, 2003
3. Results	Upon Completion of the Project
4. Discussion	Within two months of the end of the Project
5. Abstract	Within two months of the end of the project
6. Submit to MRB	
7. Submit to Journal	
a. Suggested Journal(s)	

Internal Resource Allocation (WSA, PMRL, PMI) (Man Hours)	External Resource Allocation (other PMUSA, external vendors) (Man Hours)
Kinser, 200 h; J. Amador ~40 h; Sarkar 200 h	

TO BE FILLED OUT BY WSA MANAGEMENT

☐ Approved as Written
☐ Approved with Modifications
☐ Not Approved
Reason:_____

_____
Signature of Coordinator (Date)

_____
Signature of Project Leader's Functional Director (Date)

Population Exposure Yang Chung

PM3003748897

Source: https://www.industrydocuments.ucsf.edu/docs/jplj0001